# EXHIBIT B

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

**IN RE: ETHICON, INC.,**
**PELVIC REPAIR SYSTEM**
**PRODUCTS LIABILITY LITIGATION**

**MDL No. 2327**

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**THIS DOCUMENT RELATES TO ALL**
**WAVE ONE CASES INVOLVING THE TVT-O**
**PRODUCT**

# RULE 26 EXPERT REPORT OF NEERAJ KOHLI, M.D., M.B.A

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

## I. QUALIFICATIONS

I, Neeraj Kohli, MD, MBA am a board certified Ob/Gyn and fellowship trained urogynecologist practicing strictly in the field of Urogynecology and Reconstructive Pelvic Surgery since 1997. I am board-certified in Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery. I have attached a copy of my curriculum vitae to this report. (Exhibit A)

Following graduation from Holliston High School in 1985, I entered the Accelerated Six Year Medical Combined BA/MD Program at Boston University/Boston Medical School, Boston, MA where I received my BA in 2 years and MD in 4 years. Upon graduation of my BA/MD with honors in 1991, I entered and completed a 4 year residency training in OB/Gyn at Beth Israel Hospital/Harvard Medical School. Passionate about pelvic surgery, I entered the highly regarded 2 year Fellowship in Urogynecology at Good Samaritan Hospital in Cincinnati, OH under the

mentorship of Dr. Mickey Karram, past President of the American Urogynecologic Sociey, and Dr. Mickey Baggish – both nationally and internationally recognized leaders in pelvic health medicine. Upon completion of my fellowship and after 1 year of serving as partner to Dr. Karram, I returned to Boston in July 1999 to be closer to family and to serve as Co-Director of Urogynecology at Mount Auburn Hospital-Beth Israel Hospital/Harvard Medical School and New England Medical Center/Tufts Medical School. I was also appointed Clinical Instructor in Ob/Gyn at Harvard Medical School. Upon returning to Boston, I started and served as Fellowship Director the first Urogynecology Fellowship program in Boston and at a Harvard teaching hospital. While maintaining a busy academic practice, I attended via biweekly commute and subsequently graduated from the Executive MBA Program at Kellogg Graduate School of Management (Northwestern University) in June 2002. In July 2003, I was selected to be the Founder and Chief of the Division of Urogynecology and Director of the Fellowship of Urogynecology at Brigham and Women's Hospital in Boston, and Assistant Professor at Harvard Medical School. In January 2011, I resigned from my position at Brigham and Women's Hospital to pursue private clinical practice and currently serve as Medical Director for Boston Urogyn while maintaining my academic teaching appointment at Harvard Medical School as well as my avid role as an educator and teacher in the OB/Gyn Residency Program at Brigham and Women's Hospital/Harvard Medical School. I also continue to teach nationally and internationally while maintaining an active research program in clinical Urogynecology. Since 2007 till 2015, I have been selected by my peers annually as one of the Top Doctors in America.

In my predominant role as Division Chief of Urogynecology at Brigham and Women's Hospital, I was responsible for developing and expanding the clinical, research, and educational objectives of the division. My role concentrated on high-volume clinical practice at Brigham and

Women's Hospital as well as four surrounding community hospitals-personally doing as many as 550 urogynecologic surgical cases annually. In addition, I was responsible for medical training of the general OB/Gyn residents and Urogynecology fellows in both the classroom, clinics, and operating room. Over the last decade, I have been responsible for the training of 8 fellows in urogynecology who are now established leaders in pelvic floor medicine across the country. It was also my role and responsibility to contribute to the medical literature and I have authored more than 100 scientific papers, review articles, research abstracts, clinical communications, video presentations, and scientific presentations-all related to the field of urogynecology and reconstructive pelvic surgery. Most were presented at national and international meetings and published in leading scientific medical journals - dealing with various aspects of urogynecology including disease conditions, diagnostic testing, care pathways, and surgical procedures including mesh use. Given my role as a leading academic urogynecologist and busy clinical practitioner, I have had the opportunity to serve as a clinical consultant and educator for medical product companies including Gynecare, Boston Scientific, Coloplast, CR Bard, Medtronic, Cooper Surgical, Caldera, Hologic, Uromed, SURx, and Bellybaloo. My primary role with these companies was education and research. I have also had the opportunity to participate and present at various society meetings, postgraduate courses, Grand Rounds, and clinical symposiums and cadaver labs throughout the world-teaching over 10,000 surgeons and students wholly in the field of Urogynecology.

My first experience with vaginal mesh use began in 1998 when I was among the group of first surgeons to perform the Gynecare TVT SUS in the United States. I was initially approached by Will Irby of Gynecare at our national meeting and then went to see a live case with Dr. Miklos in Atlanta. Following this, I became a preceptor and lecturer for Gynecare, educating

more than 1000 physicians on the technique of TVT suburethral sling. I worked closely with Gynecare's upper management, sales force, and professional education team. I was one of a core group of physicians that Gynecare consulted for clinical research, education, and product development. Others included John Miklos, MD, Alan Garely, MD, Vince Lucente, MD, Itzak Berger, MD, and Jake Jacabo, MD. Being one of the only academic urogynecologists in the core group, I was involved in the early stages of Gynecare when they evaluated, introduced and then further developed various products for incontinence and prolapse including the Moniitorr Urodynamic Measurement System, TVT-Obturator (TVT-O) suburethral sling, and the Prolift Pelvic Floor Repair System. I had the opportunity to research and write some of the earliest papers regarding the Gynecare product line. Most of these presentations were sponsored by Gynecare. These include the following publications and presentations:

| | |
|---|---|
| 2001 | "TVT Suburethral Sling", Vaginal Surgery Course, Beth Israel Deaconess Medical Center/Harvard Medical School, Boston, MA |
| 2001 | The TVT Technique – Current Status, 37th North American Federation Congress of the International College of Surgeons, Orlando, FL<br>Faculty Speaker |

**Kohli N**, Miklos JR, Lucente V. Tension-Free Vaginal Tape (TVT): An effective minimally invasive surgical technique for the treatment of female stress incontinence. Contemporary Ob/Gyn 1999; May: 141

Rardin C, Lucente V, Miklos JR, Heit M, Rosenblatt PL, **Kohli N**. Release of Tension Free Vaginal Tape (TVT) for the treatment of refractory postoperative voiding dysfunction. (Abstract) Int Urogyn J 2001; 12(3).

Riachi L, **Kohli N**, Miklos JR. Repeat Tension-Free Transvaginal Tape (TVT) sling for the treatment of recurrent stress urinary incontinence. Int Urogyn J 2002; 13(2): 133.

Moore RD, **Kohli N**, Miklos JR. Colpocleisis and Tension-Free Vaginal Tape (TVT) Sling for severe uterine and/or vaginal prolapse and stress urinary incontinence using local anesthesia (Videotape Presentation). (Abstract) Int Urogyn J 2002; 13(1).

Rardin CR, **Kohli N**, Miklos, et al. Tension-free Vaginal Tape (TVT) for the treatment of intrinsic sphincter deficiency with or without urethral hypermobility. (Abstract) Int Urogyn J 2002; 13(1).

Walton B, **Kohli N**, Miklos, et al. Laparoscopic Burch vs. Tension-free Vaginal Tape (TVT): A comparative cost analysis for minimally invasive treatment of stress urinary incontinence. (Abstract) Int Urogyn J 2002; 13(1).

**Kohli N**, Goldwasser S, Lucente V, McKinney T, Miklos JR, Garley A, and Karram MM. Tension Free

Vaginal Tape (TVT) for the treatment of stress incontinence: The initial North American experience. 20th Annual Scientific Meeting of the American Urogynecologic Society, San Diego, CA, October 1999.

**Kohli N**, Miklos JR. Tension Free Vaginal Tape (TVT). Video presentation. 26th Annual Scientific Meeting of the Society for Gynecologic Surgeons, New Orleans, LA, March 2000.

**Kohli N**, Miklos JR. TVT-Tension-free vaginal tape pubovaginal sling (Videotape Presentation), 25th Annual Meeting of the International Urogynecological Association, Rome, Italy, October 2000

Rardin C, Lucente V, Miklos JR, Heit M, Rosenblatt PL, **Kohli N**. Release of Tension-Free Vaginal Tape (TVT) for the treatment of refractory postoperative voiding dysfunction. 26th Annual Meeting of the International Urogynecological Association, Melbourne, Australia, December 2001.

**Kohli N**, Rardin C, Miklos JR. TVT takedown and release for postoperative voiding dysfunction (Videotape Presentation), 26th Annual Meeting of the International Urogynecological Association, Melbourne, Australia, December 2001.

Moore RD, **Kohli N**, Miklos JR. Colpocleisis and Tension-Free Vaginal Tape (TVT) Sling for severe uterine and/or vaginal prolapse and stress urinary incontinence using local anesthesia (Videotape Presentation). 27th Annual Meeting of the International Urogynecological Association, Prague, Czech Republic, August 2002.

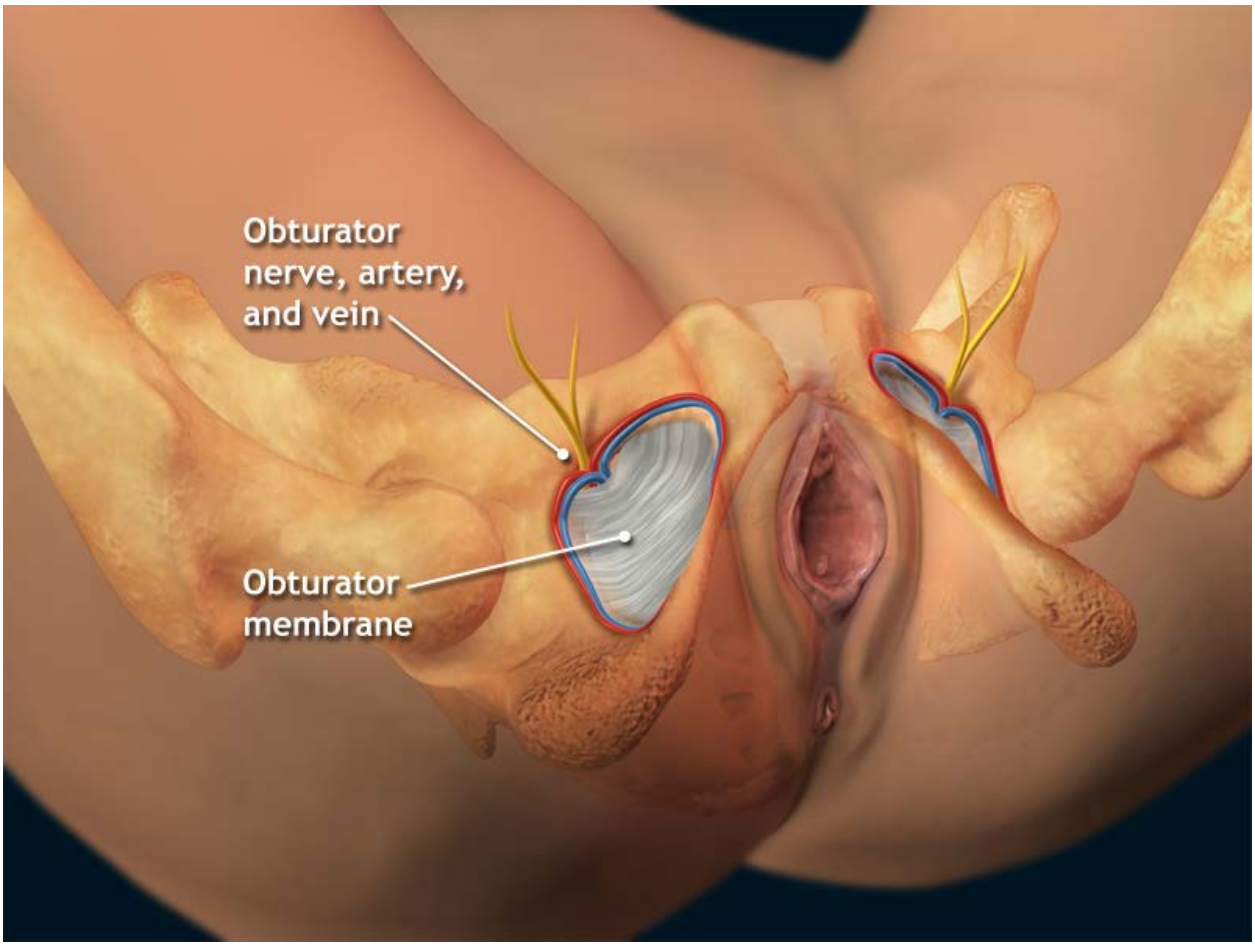
Rardin CR, **Kohli N**, Miklos, et al. Tension-free Vaginal Tape (TVT) for the treatment of intrinsic sphincter deficiency with or without urethral hypermobility. 27th Annual Meeting of the International Urogynecological Association, Prague, Czech Republic, August 2002.

Walton B, **Kohli N**, Miklos, et al. Laparoscopic Burch vs. Tension-free Vaginal Tape (TVT): A comparative cost analysis for minimally invasive treatment of stress urinary incontinence. 27th Annual Meeting of the International Urogynecological Association, Prague, Czech Republic, August 2002.

With regard specifically to TVT-O, I was one of the core group of physicians involved in early training including lectures, cadaver labs, and preceptorships. In my discussions with Gynecare regarding introduction of the TVT-O product, my sense was that it was a reactionary and compensatory move to address the competition from the traditional TOT (outside-in) sling procedure. Introduction of the TOT approach by Mentor and AMS, due to complications associated with retropubic passage of the needles and desire to recruit a more widespread user base, had threatened TVT market share which resulted in Gynecare introducing their version, TVT-O. Specifics regarding the TVT-O inside-out procedure made it, in my professional opinions, less safe than the TOT outside in, and I felt Gynecare introduced the procedure to reduce the erosion of TVT share, seem “more innovative” and also avoid patent/licensing issues. I challenged Gynecare leadership with my concerns and they justified the benefits of inside out

placement including "the procedure starts at a precise midurethral point, offers safe and accurate needle passage away from critical structures, and results and minimal dissection with the use of the safety winged guide versus finger dissection." They pointed out the dangers to the accessory obturator blood vessels associated with the outside-in approach. (Fig 1.)

**Fig 1. Anatomy of Obturator Neurovascular Bundle Used for TVT-O Teaching**




All of these "reported benefits" were not present or mentioned when Gynecare later introduced the Prolift procedure which involved passages of needles through the same obturator space into the same vaginal area but this time outside in (similar to TOT), as issues of innovation, first to

market, and patent infringement were no longer critical concerns. I remember joking with Bob Rogers, MD (anatomic teacher for Gynecare) and the Gynecare staff-"Did the female anatomy change in terms of the accessory obturator vessels when you do TVT-O vs Prolift?" They had no response. This as well as my experience with using and teaching TVT-O resulted in me slowly limiting my involvement with Gynecare beginning in 2010.

I am currently a fellow of the American College of Obstetrics and Gynecologists, and member of the American Congress of Obstetricians and Gynecologists, American Urogynecologic Society, International Urogynecological Association, and the American Association of Gynecologic Laparoscopists. I also serve as a member of the Mesh Special Interest Group of the American Urogynecologic Society which evaluates the science, data, and literature regarding vaginal mesh. I have been a journal reviewer for Obstetrics and Gynecology, the International Urogynecology Journal, Ob-Gyn Management, Journal of Reproductive Medicine, Contemporary Ob/Gyn, the Journal of Reproductive Medicine, Ob/Gyn Review, and the Journal of Female Pelvic Medicine and Reconstructive Surgery. I currently also serve as Chief Medical Officer for Emmy Medical, a medical device company which has a developed a unique 4 way catheter for diagnostic cystoscopy. In that role, I have experience and exposure in development of medical devices including FDA approval and material safety standards. Presently, I continue to be an active surgeon, teacher, entrepreneur, inventor, lecturer, and researcher.

I have reviewed numerous Instructions for Use (IFU) for a variety of medical products including mesh products in order to understand the proper way to use the devices and to gain knowledge about the complications and adverse events associated with the devices.

As a part of my clinical practice as well as my teaching roles, I have reviewed numerous Instructions for Use (IFU) for a variety of medical products, including mesh products. I have extensive clinical experience with IFUs and instructing patients about the adverse events and risks contained in IFUs and those related to surgery.

I have extensive experience with pelvic repair surgery of all types with and without biologic or synthetic materials. I have performed many pelvic surgeries for both incontinence and/or prolapse via the vaginal, abdominal, and laparoscopic approaches. I have lectured nationally and internationally regarding these surgeries, outcomes, and complications. I have also personally examined, diagnosed and treated hundreds of patients with mesh complications.

I have personally used and am familiar with the Gynecare TVT-Obturator (TVT-O) device, including its technique of insertion, efficacy, and risks. I have had the opportunity to see many patients, both mine and those of other doctors, who have undergone the TVT-O procedure and have also had the unfortunate experience of having to treat their complications. In preparing the opinions contained in this report, I have relied on my clinical experience and expertise, Ethicon corporate documents, and the peer-reviewed medical literature.

## II. SUMMARY OF OPINIONS

I hold all the opinions in this report to a reasonable degree of medical certainty.

1. The inherent properties of polypropylene mesh make it an unsuitable material for placement in the transobturator space. These include chronic inflammation, foreign body reaction, shrinkage/contraction, fibrosis, and nerve entrapment.
2. TVT-O was approved based on TVT as a predicate device although they share little clinical resemblence
3. The TVT-O was defective in its design. Various aspects of the TVT-O technique,

introduced for commercial vs clinical reasons as a response to the TOT sling and its erosion of the TVT market share, contradicts sound surgical principles. This includes blind insertion of a permanent device through the transobturator space, through and in close proximity to vital anatomic structures including muscles and nerves. In addition, the inside-out approach and the complex helical needles used with the TVT-O render the device more difficult to perform and dangerous than other "outside-in" transobturator slings. Finally, the needle passage is "blind" for approximately 3-4 cm in the TVT-O technique vs 1 cm for the TOT technique. The highest risk of complication occurs during the "blind needle passage" portion of the technique.

4. The TVT-O is difficult, if not impossible, to remove in its entirety when complications occur and warrant revision/removal. This difficulty in removal, coupled with incomplete physician education of complications and inadequate training of removal, often results on delay in diagnosis and increased risk of chronic and permanent complications.
5. When removal of the device is necessary, surgery may not correct the problems and may make them worse. Multiple surgical interventions may be required.
6. The TVT-O has an unacceptably high rate of chronic pain complications.
7. Ethicon "rushed to market" with the TVT-O in response to introduction of the "outside-in" transobturator sling from competitors. If clinical studies had been performed prior to launch, the flaws in the device would have been demonstrated.
8. Ethicon marketed the TVT-O indiscriminately to all physicians for all patients.
9. Ethicon's Instructions for Use and brochure warnings were inadequate to allow physicians to make responsible treatment choices and allow patients to give proper informed consent.

10. There are safer alternatives that are equally or more effective than the TVT-O.

11. The risks of the TVT-O outweigh its benefits.

## 1. POLYPROPYLENE MESH IS AN UNSUITABLE MATERIAL FOR TVT-O

Polypropylene is not inert when placed in the human body. The following are some examples of scientific literature reporting the properties of polypropylene and the host response. Particularly when inserted in a contaminated environment like that in the vagina, PP mesh acts as a nidus for bacteria. Studies by Vollebregt (2009) and Boulanger both demonstrated significant levels of bacterial contamination of explanted transvaginal mesh products.[1] Wang (2008) correlated bacterial contamination with de novo and refractory urge symptoms.[2] Multiple published articles describe the chronic inflammatory response and foreign body reaction observed in explanted hernia and transvaginal mesh specimens.[3] It is well-accepted in the medical and scientific literature that the mesh-tissue complex contracts and shrinks. This phenomenon was reported as early as 1998 in an animal model and was proposed s a possible

[1] Vollebregt, A., Troelstra, A., & van der Vaart, C. H. "Bacterial Colonisation of Collagen-Coated Polypropylene Vaginal Mesh: Are Additional Intraoperative Sterility Procedures Useful?". International Urogynecology Journal and Pelvic Floor Dysfunction 20, no. 11: 1345-51; Boulanger, L., M. Boukerrou, C. Rubod, P. Collinet, A. Fruchard, R. J. Courcol, and M. Cosson. "Bacteriological Analysis of Meshes Removed for Complications after Surgical Management of Urinary Incontinence or Pelvic Organ Prolapse." Int Urogynecol J Pelvic Floor Dysfunct 19, no. 6 (Jun 2008): 827-31.

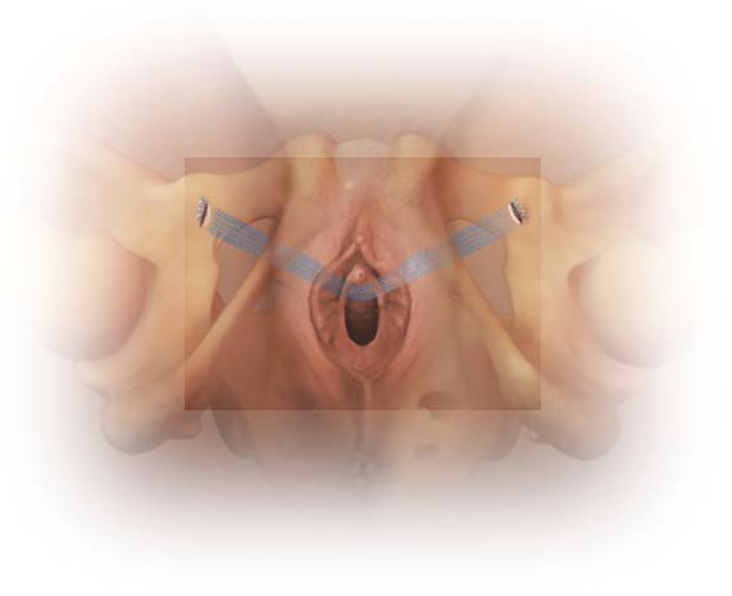
[2] Wang, A. C., R. C. Wu, C. T. Lin, and M. C. Chen. "A Microbiological and Immunohistochemical Analysis of Periurethral and Vaginal Tissue in Women with De Novo Urge Symptoms after Mid-Urethral Sling Procedures--a Prospective Case-Controlled Study." Int Urogynecol J Pelvic Floor Dysfunct 19, no. 8 (Aug 2008): 1145-50.

[3] Elmer, C., B. Blomgren, C. Falconer, A. Zhang, and D. Altman. "Histological Inflammatory Response to Transvaginal Polypropylene Mesh for Pelvic Reconstructive Surgery." J Urol 181, no. 3 (Mar 2009): 1189-95; Smith, T. M., S. C. Smith, J. O. Delancey, D. E. Fenner, M. O. Schimpf, M. H. Roh, and D. M. Morgan. "Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center." Female Pelvic Med Reconstr Surg 19, no. 4 (Jul-Aug 2013): 238-41; Klosterhalfen B, Linge U, Rosch R, Junge K. "Long-Term Inertness of Meshes." In Meshes: Benefits and Risks. Germany: Schumpelick V, Nyhus L, 2003; Klosterhalfen, B., K. Junge, and U. Klinge. "The Lightweight and Large Porous Mesh Concept for Hernia Repair." Expert Rev Med Devices 2, no. 1 (Jan 2005): 103-17.

explanation for secondary folding in cases of poor elasticity and small pores.[4] In a 2005 Gynemesh study, the authors found shrinkage of the mesh in 3 patients and this shrinkage was associated with severe dyspareunia and severe pain.[5] Fibrotic bridging was found closely associated with the occurrence of shrinkage.[6] In 2009, Letouzey et al reported on the shrinkage rate of Gynemesh after implantation for cystocele repair over a 9 year period in 40 patients evaluated with ultrasound. They found a 10% per year shrink rate up to 85% at 8 years.[7] Gynecare Gynemesh PS has been found to have a higher stiffness when compared to other meshes. Stiffness has been shown to associated with complications, including erosion.[8] These findings are especially relevant for TVT-O given the arms of the mesh pass just under the vaginal sulcus and then thru the obturator fascia including the obturator intrnus and externus muscles bilaterally.

**Fig. 2. Location of TVT-O Mesh in the Vagina**

[4] Klosterhalfen, B., K. Junge, and U. Klinge. "The Lightweight and Large Porous Mesh Concept for Hernia Repair." Expert Rev Med Devices 2, no. 1 (Jan 2005): 103-17.
[5] de Tayrac, R., A. Gervaise, A. Chauveaud, and H. Fernandez. "Tension-Free Polypropylene Mesh for Vaginal Repair of Anterior Vaginal Wall Prolapse." J Reprod Med 50, no. 2 (Feb 2005): 75-80.
[6] Klosterhalfen, B., K. Junge, and U. Klinge. "The Lightweight and Large Porous Mesh Concept for Hernia Repair." Expert Rev Med Devices 2, no. 1 (Jan 2005): 103-17.
[7] Letouzey, et al., "Is Polypropylene mesh coated with aantibiotics IS Efficient to Prevent Mesh Infection and Contraction in an Animal Infectious Model?" Int Urogyn J 2009;20(Suppl.2):S205-6.
[8] Jones, KA. "Tensile properties of commonly used prolapse meshes." Intt Urogyn J Pelvic Floor Dysfunction 20: 847-53 (2009); M Huebner et al. "The use of graft materials in vaginal pelvic floor surgery." Int J Obstet Gynecol 92:279-88 (2006).



The properties of polypropylene mesh, especially the higher weight, smaller pore Prolene mesh used in the TVT-O, is unsuitable for use in the transobturator space. The procedure requires blind placement through multiple muscles and in close proximity to large and small nerves. The body's reaction to the mesh creates chronic inflammation, foreign body reaction, shrinkage/contraction, fibrosis, nerve entrapment, and deformation. These properties have clinical significance and can result in immediate or delayed onset complications after placement of the TVT-O mesh including erosion/exposure, mesh arm banding, dyspareunia/chronic pain, vaginal scarring/deformation, sexual impairment, and neurologic complications of the vagina, groin, and lower extremities.

2. **TVT vs TVT-O**

The Gynecare TVT Obturator was cleared by the FDA in December, 2003. Ethicon described the TVT-O as a "modification to Tension-free Vaginal Tape (TVT) System". The predicate device was the Gynecare retropubic TVT. The device contains the same PROLENE

mesh as TVT and was designed to treat the same condition, stress urinary incontinence. Otherwise, it is a completely different device inserted into a different space with a different technique using different instruments and associated with a different set of complications. In a discussion of the substantial equivalence, Ethicon claimed these similarities:

- Has the same indications
- Uses the same operating principles
- Incorporates the same basic design

The two devices are made of the same polypropylene material and are both used to treat stress urinary incontinence, but are otherwise unrelated in terms of anatomy, instrumentation, procedural details, and associated complications. The IFU for TVT-O is noted below.

# GYNECARE TVT *Obturator* Atraumatic Winged Guide, Sterile Single Use

**Please read all information carefully.**

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

**Important:**

This package insert is designed to provide instructions for use of the GYNECARE TVT* *Obturator* System, including the GYNECARE TVT *Obturator* device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT *Obturator* device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

## DESCRIPTION

The GYNECARE TVT *Obturator* System is a sterile, single patient use procedure kit consisting of:

### GYNECARE TVT Obturator device

The GYNECARE TVT *Obturator* device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

### GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT *Obturator* device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT *Obturator* device. The Helical Passer MUST not be bent or deformed in any way.

### GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

## INDICATIONS

The GYNECARE TVT *Obturator* device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

## INSTRUCTIONS FOR USE

**(Note: hand positions shown in illustrations may vary)**

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. Optionally, the labia may be sutured laterally to provide exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. *(See Figure 1)*

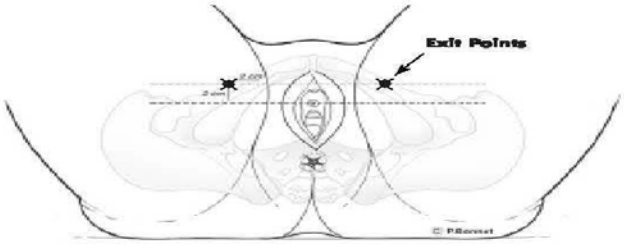



**FIG. 1**

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

***(Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)***

Using a "push-spread technique", begin blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented either on the horizontal plane or with the tips pointed slightly upward *(See Figure 2)*. Continue dissection toward the "junction" between the body of the pubic bone and the inferior pubic ramus. *(See Figure 2)*

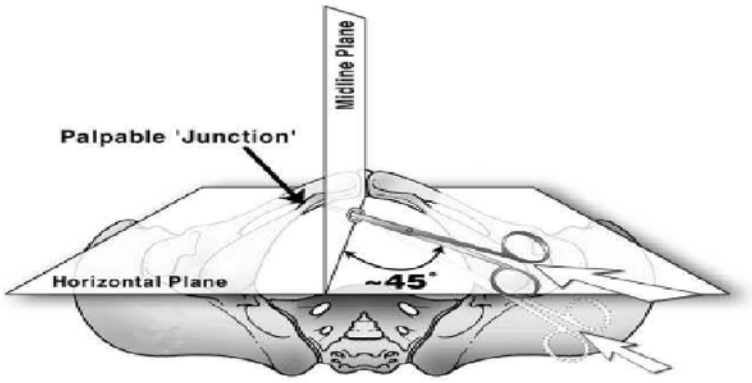



**FIG. 2**

When the "junction" between the body of the pubic bone and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the GYNECARE TVT Winged Guide from the package. *(See Figure 3)*

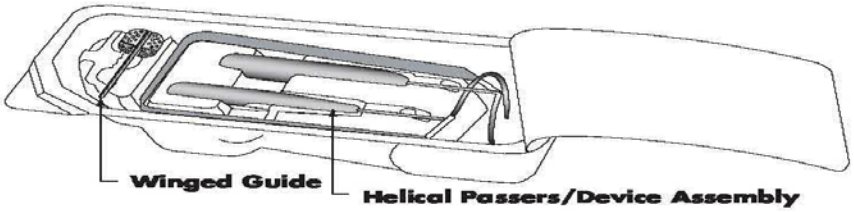



**FIG. 3**

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

***(Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)***

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT *Obturator* device assembly from the sterile pack *(See Figure 3 for components).*

***(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)***

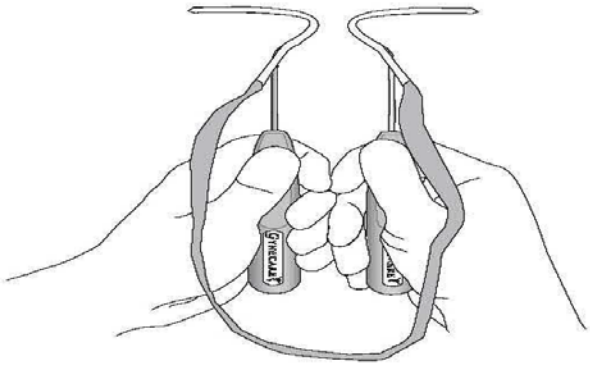


**FIG. 4**

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.

11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. *(See Figure 5)*

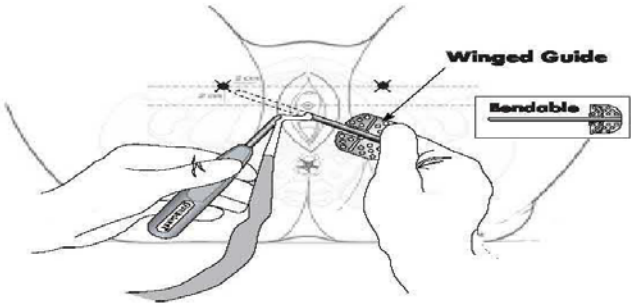



**FIG. 5**

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

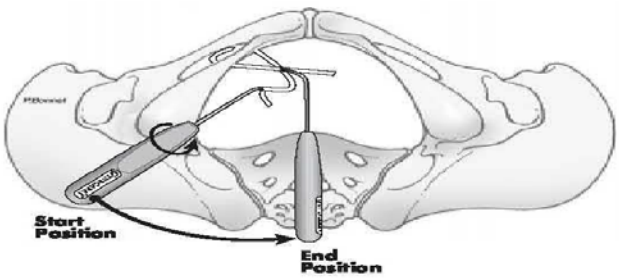



**FIG. 6**

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer simultaneously as you move the handle towards the midline. *(See Figure 6)* ***(Note: Never allow the handle to be orientated in a horizontal position.)***

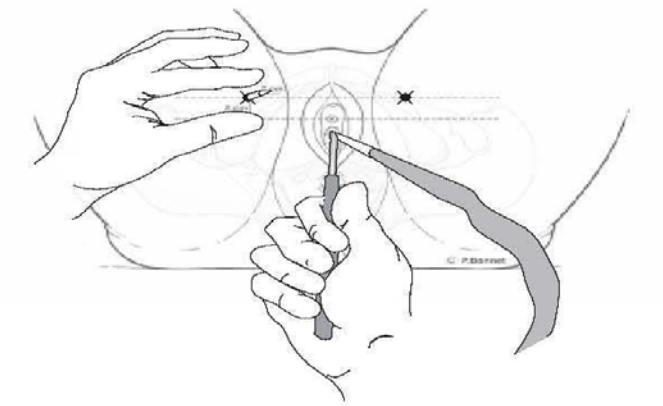


**FIG. 7**

14. The point of the Helical Passer should exit near the previously determined exit points *(See Figure 7)*. However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the helical passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp it with a clamp and, while stabilizing the tube near the urethra remove the Helical Passer by a reverse rotation of the handle. *(See Figure 8)*

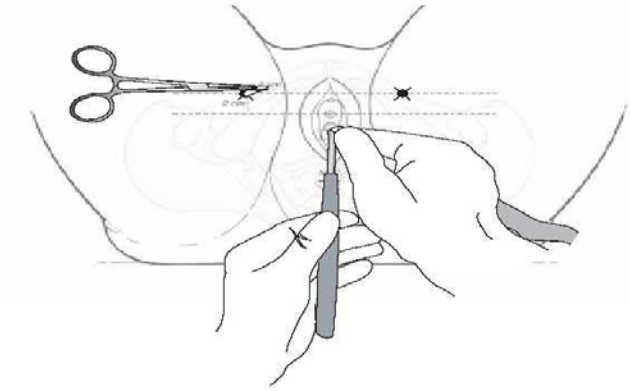


**FIG. 8**

15. Pull the plastic tube completely through the skin until the tape appears. *(See Figure 9)*

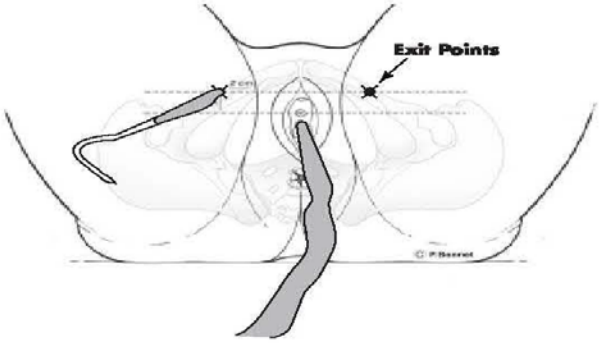



**FIG. 9**

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. *(See Figure 10)*

***(Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)***

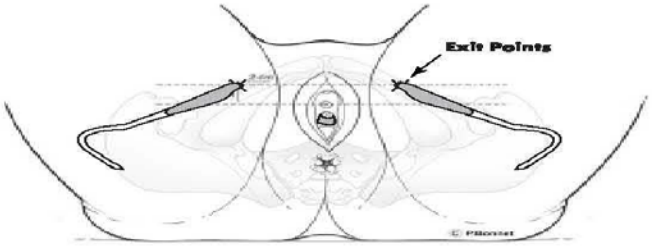



**FIG. 10**

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the mid-urethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. (*See Figure 11)*

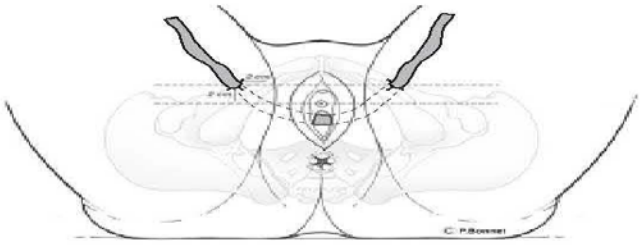


**FIG. 11**

When the tape is in position, remove the plastic sheath that covers the tapes. To avoid positioning the tape with tension, place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths.

***(Note: Premature removal of the sheath may make subsequent adjustments difficult.)***

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.

19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

**CONTRAINDICATIONS**

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

**WARNINGS AND PRECAUTIONS**

- Do not use GYNECARE TVT *Obturator* procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT *Obturator* procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT *Obturator* procedure before employing the GYNECARE TVT *Obturator* device.
- Acceptable surgical practice should be followed for the GYNECARE TVT *Obturator* procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT *Obturator* procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.

- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, in case of pregnancy delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT *Obturator* System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT *Obturator* device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

**ADVERSE REACTIONS**

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

**ACTIONS**

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

**HOW SUPPLIED**

The GYNECARE TVT *Obturator* System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

**STORAGE**

Recommended storage conditions for the GYNECARE TVT *Obturator* System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

*CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.*

ETH.MESH.02340829.

### 3. TVT-O IS DEFECTIVE IN ITS DESIGN

With the introduction of TVT in 1998, Gynecare became the market leader in the minimally invasive sling market. However, retropubic passage of the TVT needles was associated with damage to the retropubic structures including bladder, bowel, and blood vessels. The transobturator approach was introduced by Delorme in 2001 in order to reduce injury to the retropubic structures. Gynecare had the opportunity to research and acquire the original TOT procedure but felt their dominant position backed by history in TVT was immune to sales pressure. It was not till after TOT began to erode market share, did Gynecare eventually introduce an obturator approach, TVT-O. Unfortunately, TVT-O was a defective product but was acquired nonetheless by Gynecare due to competitive pressure, need to maintain an "innovator image", and difficulty with patent protection. This is well summarized by Dr. Axel Arnaud, Medical Affairs Director for Ethicon, in his internal Gynecare document entitled "History of TVT-O". In it , he says Delorme unfortunately did not meet the right people at Gynecare and received a "no-go" decision which resulted in him selling the product to Mentor. A similar technique developed by Mellier was sold to AMS. These products became Obtape and Monarc, respectively. "It was obvious that the transobturator approach was "better" than the retropubic and the company entered a critical phase of its existence since TVT was responsible for 65% of the sales. He "finally found a Belgian Professor who was "offering a clever modification of the transobturator approach." He felt "it would be a great way for late entering the transobturator market without losing (their) image of an innovative company." [9]According to internal Gynecare documents entitled "Due Diligence Growth Opportunity Outline" dated February 2003 and

[9] ETH.MESH.03932911

regarding Project Mulberry (TVT-O) "The rationale for project Mulberry is to drive and defend GYNECARE sales of TVT™ …. TVT™ is under competitive pressure, as evidenced by a decline in category share of revenue of 15%, in Europe and the US, over the last 2 years…...A surgeon at the University of Liege (Belgium) has developed and filed (August 2002) for a US patent for a technique and devices for insertion of a mid-urethral sling through the obturator hole. Existing IP covers the outside-in approach, but his inside-out approach (TOVT) removes (virtually to 0%, the risk of bladder perforation) compared to 5-8% with TVT. We predict a continued risk to our TVT franchise if we do not introduce a competitive obturator approach and we estimate the lost profit has a present value (PV) of $8.0MM."[10] According to internal Gynecare documents, "Due to the aggressive competitor activity and highly adopted transobturator approach, Gynecare TVT lost considerable market share in 2003. With the launch of TVT-O in Jan 04, Gynecare now has the opportunity to further develop and drive market leadership of the Gynecare TVT Brand." The same document acknowledges "The TVT-O clinical and publication data strategy for TVT-O is at present very week-reliant on Prof de Leval observational data under spinal anesthesia."[11] TVT-O was rushed to market without adequate long term studies regarding safety and efficacy. Gynecare used the data regarding their mesh used in TVT and combined it with data regarding other TOT products, but never had adequate data regarding safety efficacy for the specific TVT-O product (instrumentation/sling material and inside-out approach) In fact, the only limited studies available at the time of launch were done by Dr. Jean De Leval. These were limited small number observational studies offered by the inventor who had strong financial incentive show his product worked so it could be acquired for millions of dollars. In December 2003, Martin Weisberg, MD, Medical Director of Gynecare

[10] ETH.MESH.06873447
[11] ETH.MESH.05793740

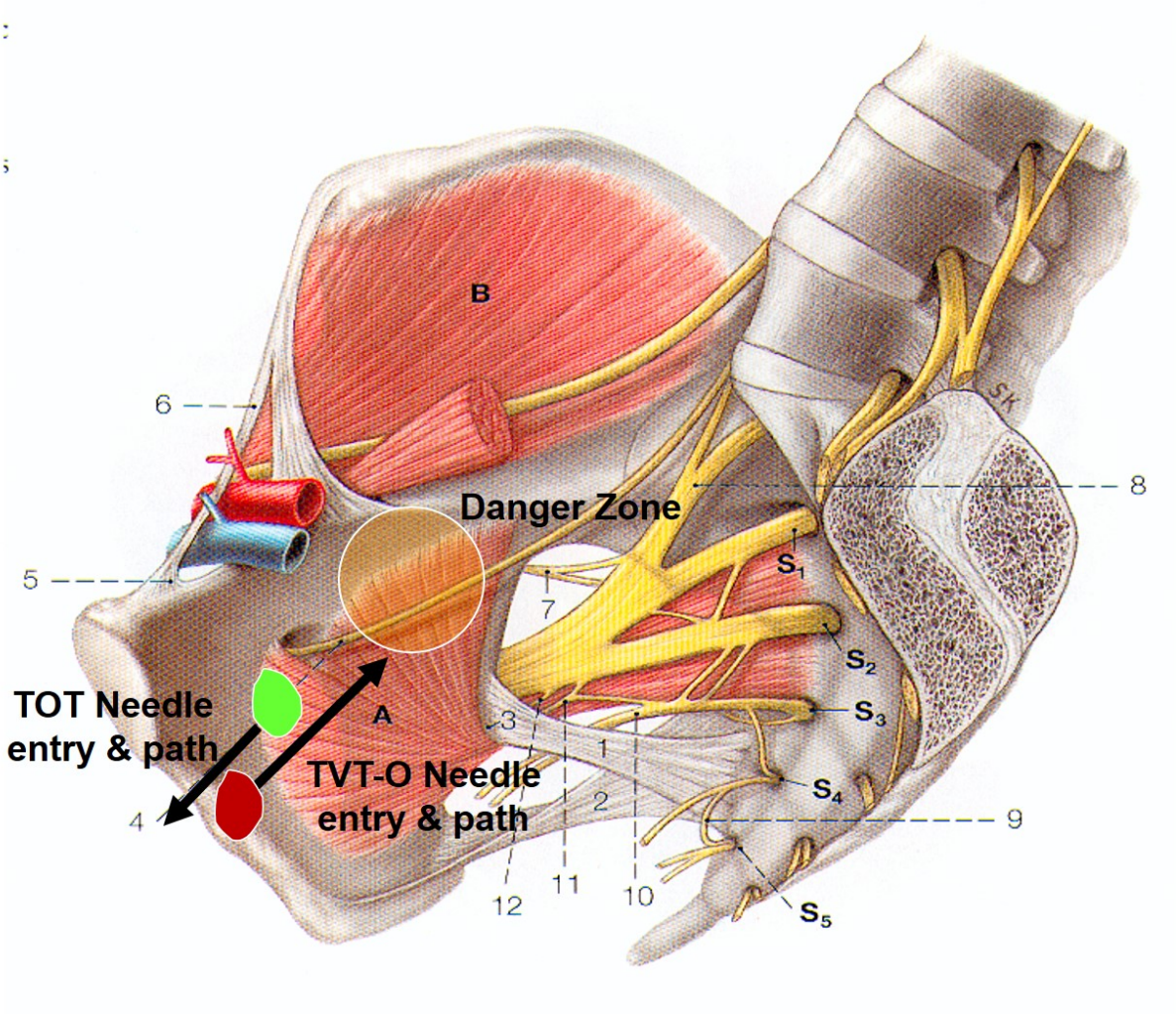
issued a Clinical Expert Report summarizing these findings. Based only on De Leval's one observational study and one comparative study comparing 138 TVT-O cases and 134 TVT case (which was unpublished and incomplete) and using previous outcomes and anatomic data regarding TOT outside in as a surrogate for TVT-O, Gynecare Medical Director concluded "The transobturator "inside-out" approach to implementing a polypropylene mesh results in the identical placement of the tape as in the "outside-in" procedure. This, coupled with the results of De Leval's "inside-out" study data, indicates that the efficacy is equivalent…….is performed under direct visualization. The "inside-out" transobturator technique therefore seems more precise than previous techniques, appears easy to perform, is reproducible, may not require cystoscopy, and is likely to result in fewer complications. The result in terms of curing incontinence seem to be equal to the techniques described previously in the short term. Based on the above, I am confident that the "inside-out" transobturator approach…..is safe and effective and that additional clinical studies are not necessary at this time." The device was released in response to competitive pressures without adequate evaluation or safety information.[12]

The TVT-O device is inserted using an inside-outside surgical approach not used in other transobturator slings. It is inserted through a minimal vaginal incision using a winged guide and exits thru the following anatomical structures: pubocervical fascia, obturator internus muscle, obturator membrane, obturator externus muscle, adductor magnus muscle, adductor brevis muscle, gracilis muscle, and fascia lata. As the needle passes through its course, it is close to or passes through an area of many nerves and blood vessels which can be injured and cause complications. As opposed to the TOT needle passage, TVT-O needle passage towards not away

[12] ETH.MESH.00259643

from critical neurovascular structures including the obturator nerve which, if injured, can case groin/leg/vaginal pain. (Fig 3)

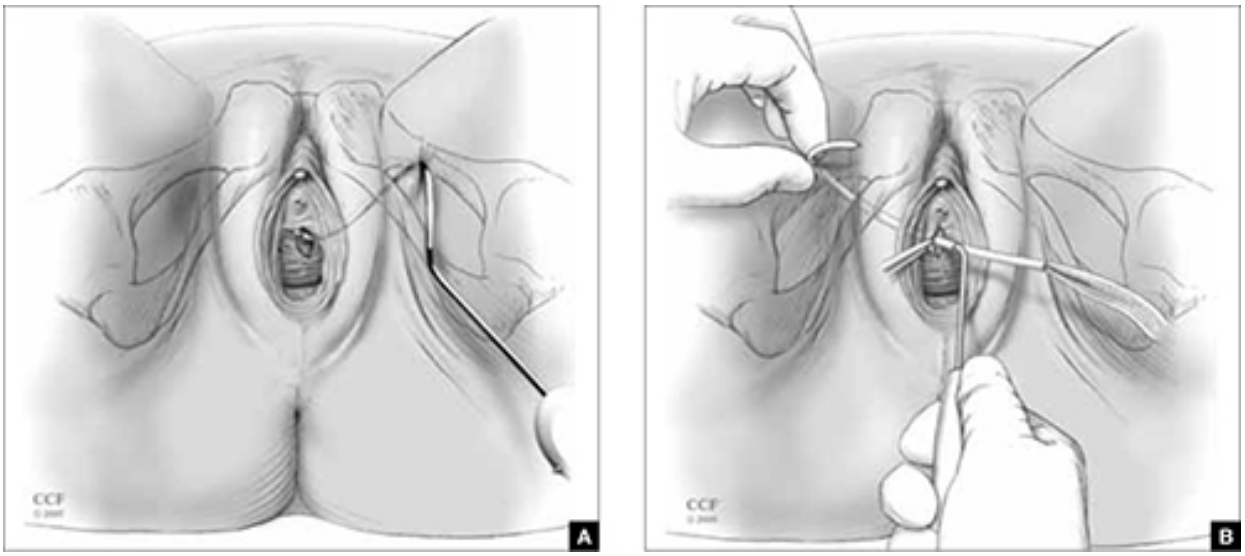
**Fig. 3. Comparison of TVT-O vs TOT Needle Passage and Critical Structures**




In addition, the technique of the inside-out approach makes exact passage and exit of the needle imprecise and dangerous as the “blind needle passage” from needle tip insertion to removal is approximately 3-4 cm vs 1 cm in the outside-in approach. In the outside-in approach, vaginal dissection allows insertion of the surgeon’s finger to provide a safety backstop while inserting

the needle. The TVT-O is associated with minimal dissection and blind insertion of a winged guide to help placement of the needles.

**Fig. 4. TOT (left) vs TVT-O (right) Needle Insertion**

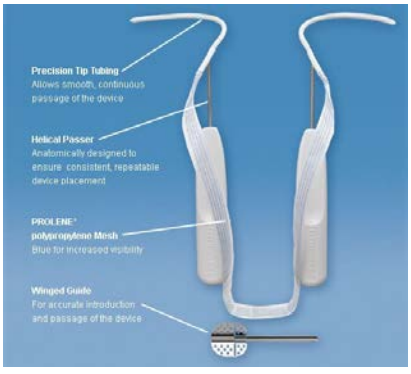



Finally, the transobturator space was traditionally foreign to gynecologists and urologists; no other previous pelvic reconstructive procedure utilized the space distal to the transobturator foramen.

In addition, the helical instruments necessary to insert the TVT-O using the inside-to-out approach are complicated and complex. Compared to the needles for the "outside-in" approach, the TVT-O "inside-out" needles are spatially more complex and less predictable.

**Fig. 5 TOT vs TVT-O Needles**

TOT Needles




TVT-O Needles

This instrumentation makes it difficult to determine the exact location of the needle tip and insert the TVT-O into the correct space, creating a very small margin of error, especially with surgeons unfamiliar with the anatomy of the transobturator space. I discovered these problems with the design of the TVT-O first-hand early on serving as faculty teaching a cadaver course for Gynecare. In this course, one of the participants, May Wakamatsu, MD (a highly experienced urogynecologist and Chief of Urogynecology at Massachusetts General Hospital) was unable to place the TVT-O in the correct position – mistakenly inserting it into the retropubic space.[13] Following this lab, I expressed my concerns to members of the Gynecare team and reduced my use of TVT-O as well as my involvement in teaching of the technique. This difficulty is also reflected in the peer-reviewed literature.[14] Gynecare was well aware of the concerns physicians had regarding the defective device as detailed above. In a an internal document titled "TVT Key Selling Points Versus Competitors", the acknowledge negative feedback from physicians including "don't like wing guide, don't like inside-out because you can't palpate needle, perceived blind passage making it less safe, persistent thigh pain, not as easy to use, risk of vascular & nerve damage."[15]

Additionally, the device is difficult, if not impossible to remove. Multiple procedures may be required and surgical correction may not correct the problems and may even make symptoms worse. These flaws in the design of the TVT-O contradict sound surgical principles.

[13] Gynecare TVT-O Cadaver Lab, Newton-Wellesley Hospital, Newton, MA

[14] E.g., C. Reisenauer et al., "Transobturator Vaginal Tape inside-Out. A Minimally Invasive Treatment of Stress Urinary Incontinence: Surgical Procedure and Anatomical Conditions," *Eur J Obstet Gynecol Reprod Biol* 127, no. 1 (2006); J.P. Spinosa, Dubius P.Y.E, Riedrer B., "Transobturator Surgery for Female Urinary Continence: From Outside to inside or from inside to Outside? A Comparative Anatomic Study. ," *Prog Urol* 15, no. 4 (2005); P. Hubka et al., "Anatomical Relationship and Fixation of Tension-Free Vaginal Tape Secur," *Int Urogynecol J Pelvic Floor Dysfunct* 20, no. 6 (2009); P. Hinoul et al., "Anatomical Variability in the Trajectory of the inside-out Transobturator Vaginal Tape Technique (Tvt-O)," ibid.18, no. 10 (2007).

[15] ETH.MESH.03983705

This is borne out in my experience caring for patients with complications related to transobturator slings, as well as the peer-reviewed medical literature.[16]

Polypropylene mesh devices like the TVT-O are associated with complications not seen or seen with much less frequency compared to other non-mesh surgical treatments for SUI. These complications can be life-altering and may require multiple procedures to correct, sometimes with permanent or chronic complications. These include vaginal, urethral, and bladder mesh erosion, urethral obstruction, foreign body infection/reaction, and refractory dyspareunia or chronic pain. In the case of the TVT-O, the rates and severity of these complications, particularly pain are unacceptably high.[17] These complications are inherent in the design of the device and usually do not indicate surgical error or faulty technique on the part of the implanting surgeon.

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[16] E.g., J. G. Blaivas, Purohit, R. S., Weinberger, J. M., Tsui, J. F., Chouhan, J., Sidhu, R., & Saleem, K., "Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications," *The Journal of Urology* 190, no. 4 (2013); J. M. Danford et al., "Postoperative Pain Outcomes after Transvaginal Mesh Revision," *Int Urogynecol J* 26, no. 1 (2015); M. A. Denman et al., "Reoperation 10 Years after Surgically Managed Pelvic Organ Prolapse and Urinary Incontinence," *Am J Obstet Gynecol* 198, no. 5 (2008); W.S. Reynolds, Kit, L., Kaufman, M.R., Karram, M., Bales, G.T., and Dmochowski, R., "Obturator Foramen Dissection for Excision of Symptomatic Transobturator Mesh," *The Journal of Urology* 187, no. 5 (2012); L. Rogo-Gupta, "Current Trends in Surgical Repair of Pelvic Organ Prolapse," *Curr Opin Obstet Gynecol* 25, no. 5 (2013); D. Lee, C. Bacsu, and P. E. Zimmern, "Meshology: A Fast-Growing Field Involving Mesh and/or Tape Removal Procedures and Their Outcomes," *Expert Rev Med Devices* (2014); E. Petri and K. Ashok, "Comparison of Late Complications of Retropubic and Transobturator Slings in Stress Urinary Incontinence," *Int Urogynecol J* 23, no. 3 (2012).

[17] E.g. C. R. Chapple et al., "Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward," *Eur Urol* 64, no. 4 (2013); Maxwell M Zoorob R, South M, "Vaginal Colpopexy Using a Trocar-Less Mesh Kit Versus Traditional Uterosacral Ligament Suspension: A Retrospective Cohort Study," *Female Pelvic Med Reconstr Surg* 17, no. 5 Suppl 2 (2011); S. Abbott et al., "Evaluation and Management of Complications from Synthetic Mesh after Pelvic Reconstructive Surgery: A Multicenter Study," *Am J Obstet Gynecol* 210, no. 2 (2014); Deng DY Barski D, "Management of Mesh Complications after Sui and Pop Repair: Review and Analysis of the Current Literature," *BioMed Research Intl.* Article ID 831285 (2014); Blaivas, "Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications."; J. G. Blaivas et al., "Safety Considerations for Synthetic Sling Surgery," *Nat Rev Urol* 12, no. 9 (2015); E. C. Crosby et al., "Symptom Resolution after Operative Management of Complications from Transvaginal Mesh," *Obstet Gynecol* 123, no. 1 (2014); G. E. Dunn et al., "Changed Women: The Long-Term Impact of Vaginal Mesh Complications," *Female Pelvic Med Reconstr Surg* 20, no. 3 (2014); J. Hammett et al., "Short-Term Surgical Outcomes and Characteristics of Patients with Mesh Complications from Pelvic Organ Prolapse and Stress Urinary Incontinence Surgery," *Int Urogynecol J* 25, no. 4 (2014); B. L. Hansen et al., "Long-Term Follow-up of Treatment for Synthetic Mesh Complications," *Female Pelvic Med Reconstr Surg* 20, no. 3 (2014); Ahlalabi F Hou JC, Lemack G, Zimmern PE, "Outcome of Trans-Vaginal Mesh and Tape Removed for Pain Only," *J Urol* 192, no. 3 (2014); Danford et al., "Postoperative Pain Outcomes after Transvaginal Mesh Revision."; Denman et al., "Reoperation 10 Years after Surgically Managed Pelvic Organ Prolapse and Urinary Incontinence."; Reynolds, "Obturator Foramen Dissection for Excision of Symptomatic Transobturator Mesh."; Rogo-Gupta, "Current Trends in Surgical Repair of Pelvic Organ Prolapse."

## 4. TVT-O AND PAIN COMPLICATIONS

The signature complication with the TVT-O device is pain – dyspareunia and pelvic pain. Pain is sometimes transient, but can also be chronic and permanent. It can be related to passage of the sling mesh thru or in the vicinity of anatomic structures or due to banding of the mesh arms in the anterior vaginal sulcus. It can occur in the pelvis, groin, leg, vagina, and buttocks. It can occur immediately following surgery or develop insidiously over time. It can be disabling and interfere with functions of daily living including walking, joint movement, or sitting. It is often described as neuropathic (indicating nerve dysfunction, injury, or damage) or as a chronic pain syndrome resulting in regional or systemic symptoms. There is often delay in diagnosis as surgeons were not adequately informed or trained by Gynecare based on my experience in its diagnosis, management, or surgical treatment. It is often unresponsive to traditional treatment modalities and sometimes refractory to treatment of any kind. It may be associated with vaginal exposure or erosion, but not necessarily. There is often pain noted on vaginal exam especially in the area of the mesh arms. The levator muscles may also be affected causing generalized pelvic and vaginal pain, dyspareunia, and pain with prolonged standing. Sexual pain and impairment due to the TVT-O device is common and different from discomfort associated with other conditions such as vaginal atrophy, pelvic organ prolapse, and vaginal infections. It is not infrequent for the pain or mesh banding to preclude sexual intercourse completely. Exam findings are characteristic of mesh-related pain and include allodynia and hyperalgesia, vaginal distortion and shortening, palpable bands, tenderness to palpation over the mesh, scarring, and muscle spasm. Surgical correction fails to alleviate the symptoms in a large percentage of women and may even make the patient's condition worse. Multiple surgeries may be

necessary.[18] These pain complications are seen much less frequently and much less severely with slings that are placed in the retropubic space.[19]

Pain complications associated with the TVT-O were discovered early on. The inside-out technique was developed by Professor de Leval in Belgium, who performed the first procedures and was funded by Ethicon. Even in de Leval's original series, postoperative groin and leg pain was a common occurrence, occurring in 26 percent of cases.[20] Also, some of de Leval's early patients experienced pain that was severe and extended beyond the postoperative period.[21] These pain issues were not seen with the same high frequency or level of intensity with retropubic slings or even outside-in transobturator slings.

During the design phase, Ethicon employees raised the question as to whether the high rate of pain complications warranted a design change. Zenobia Walji wrote:

> "I wanted to be sure that you were made aware of this concern re transient leg pain….I do think we need to hash out some solutions to this clinical issue:

[18] E.g., Robinson Dep. (9/11/13) 1138:7-11.
[19] E.g., H. J. Cholhan, T. B. Hutchings, and K. E. Rooney, "Dyspareunia Associated with Paraurethral Banding in the Transobturator Sling," *Am J Obstet Gynecol* 202, no. 5 (2010)., L. Rogo-Gupta and S. Raz, "Pain Complications of Mesh Surgery," in *Complications of Female Incontinence and Pelvic Reconstructive Surgery*, ed. H.B. Goldman, Current Clinical Urology; S. H. Boyles et al., "Complications Associated with Transobturator Sling Procedures," *Int Urogynecol J Pelvic Floor Dysfunct* 18, no. 1 (2007); J. Duckett and A. Baranowski, "Pain after Suburethral Sling Insertion for Urinary Stress Incontinence," *Int Urogynecol J* 24, no. 2 (2013); F. Daneshgari, W. Kong, and M. Swartz, "Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials," *J Urol* 180, no. 5 (2008); S. Ross et al., "Transobturator Tape Compared with Tension-Free Vaginal Tape for Stress Incontinence: A Randomized Controlled Trial," *Obstet Gynecol* 114, no. 6 (2009); R. Teo et al., "Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women," *J Urol* 185, no. 4 (2011); A. C. Kirby, J. Tan-Kim, and C. W. Nager, "Midurethral Slings: Which Should I Choose and What Is the Evidence for Use?," *Curr Opin Obstet Gynecol* 27, no. 5 (2015).
[20] E.g., ETH.MESH.00259634 at 9638.
[21] E.g., Weisberg Dep. (5/30/13) 197:17-198:7.

1) Thoroughly understand the cause-effect of this complication – is it related to consistency of technique?
2) Can we avoid this clinical complication by changing technique (i.e. fine tuning the IFU)?
3) If the above two "reasons why" do not resolve this clinical outcome, then is there a design change that could avoid this complication? If yes, do we wait to make this change in the next gen product, or pursue the change now?"[22]

Ethicon did not perform any testing to determine the "reasons why" because Ethicon did not take the time it would require. Ethicon instead took a very aggressive development course. Originally, the TVT-O was projected to need 24 months to complete. However, the product ended up being released in just nine months – "a new record for Gynecare."[23] This aggressive schedule to sales was deemed "critical to GYNECARE's success in the marketplace."[24] In another email, a marketing employee stated, "To protect our market share, we need to be ready to launch – so the development process should not require clinicals."[25] In my opinion, if clinical trials had been performed, the outcomes and complications in the TVT-O design would have become apparent.

After product introduction, pain was acknowledged many times by Gynecare officials but its frequency, severity, impact, and treatment were minimized. In July 2011, in response to Gynecare emails regarding Dr. Jackson's patient, Piet Hinoul, MD, PhD and Medical Affairs Director, Worldwide for Ethicon, Women's Health and Urology writes "While we have not

[22] E.g., ETH.MESH.03803462.
[23] ETH.MESH.06892171.
[24] ETH.MESH.02180737.
[25] ETH.MESH.00260591.

performed clinical trials evaluating treatment measures for patients with thigh pain we do have anecdotal reports as well as information from the literature regarding the potential cause and management of this condition. Pain after sub-urethral sling using TVT-O can result from a number of factors including tape placement, tissue reaction, closure method , hematoma formation or infection to name a few . The above articles will provide you with the anatomic knowledge that should make it easier to consider further evaluation and treatment of your patient. The paper by Roth suggests the type of evaluation and treatments that might be considered in your patient. The differential diagnosis includes adductor muscle strain, osteitis pubis, trochanteric bursitis, obturator/groin abscess, inflammation and edema or nerve entrapment of the anterior branch of the obturator nerve, and structural adhesions . Should analgesics, NSAIDS, and physical therapy fail the authors have suggested the use of steroid and local anesthetic . Other options include localized excision of mesh."[26]

Immediately after TVT-O was released, Ethicon began receiving complaints regarding incidents of groin and leg pain. Dr. Charlotte Owens, Medical Affairs Director, received these calls and made the determination that that the pain complications were rare and not the fault of the device.[27] She was not aware, however, that a "confidential meeting" took place in Belgium on March 22, 2004 – just three months after the TVT-O launch – with Prof. de Leval and Ethicon executives. The purpose of this meeting was to discuss possible modifications of the TVT-O to

[26] ETH.MESH.04056609

[27] Owens Dep. (6/20/13)) 436:17 to 437:9; *See also* Owens Dep. (6/20/ 13) 444:6-445:2 ("Q: So we've just gone through, one, two -- five or so complaints that you received in a one- or two-month period in 2005, and they're all about leg pain associated-- leg or groin or thigh pain associated with the TVT-0, correct? A Correct. Q And in each instance, you determined that it was not related to the device, correct, except maybe that last one? A I think I said that I couldn't link it definitively or some other terms like that, so I'm not sure that there was a final conclusion. Q Now, you also used the phrase "rarely" a number of times. A Yes. Q Do you remember that? And you used "transient." A Yes. Q "Rarely occurs during TVT-0 procedure," that's what you said, right? A Yes).

reduce pain.[28] The modification involved Removal of the segment of the tape that passes through the adductor muscles (possibly causing post-operative pain?): the tape length would be reduced to approximately 12 centimeters. Both ends of the tapes would be attached to a nylon suture, creating a loop at the tape's ends, and ending as a single string at its distal extremity. This modification, of course, became the prototype for a new Ethicon product, TVT Abbrevo. No modifications were ever made to the TVT-O and doctors were never informed of the concerns.

Prof. de Leval began a randomized trial comparing the modification with the original TVT-O in January, 2007. He found that the modification had similar efficacy to the TVT-O, but significantly reduced postoperative groin pain. Prof. de Leval concluded the following regarding pain associated with the TVT-O: "The source of groin pain after transobturator procedures may originate from trauma secondary to the penetration of the dissecting scissors, needles, and/or tape into muscular (i.e., obturator and adductor muscles) and/or aponeurotic (i. e., obturator membrane) structures. It could also be related, however, to the foreign body reaction to the tape, possibly in proximity to peripheral obturator nerve branches."[29]

These results, however, were not published until 2011 and not shared with physicians until TVT Abbrevo was launched in 2010. In marketing Abbrevo to sales force, Ethicon acknowledged that "TO slings are associated with post-operative groin pain", "18-20 cm. mesh traverse[s] adductor muscles, pass[es] near peripheral obturator nerve branches", and "can cause foreign body

[28] ETH.MESH.02180759, ETH.MESH.03803462, ETH.MESH.00632022, and Owens Dep. (6/20/13) 453:24 to 460:19.

[29] J. de Leval, A. Thomas, and D. Waltregny, "The Original Versus a Modified inside-out Transobturator Procedure: 1-Year Results of a Prospective Randomized Trial," *Int Urogynecol J* 22, no. 2 (2011).

response".[30] The IFU only states, Transient leg pain lasting 24-48 hours may occur and can usually be managed with mild analgesics.[31]

The unique design of the TVT-O helical needles and the required trajectory makes placement extremely difficult and patient injuries more likely. I discovered this first-hand when I taught a cadaver course early on following the introduction of the TVT-O. The participants had trouble placing the device in the correct location. This difficulty is also borne out in the peer-reviewed medical literature. For example, Spinosa (2007) determined in a cadaver study that the "inside-out route, as described by its inventor, has a greater risk of surgical injury compared to the "outside-in" approach.[32] The more lateral exit point puts the pudendal vascular bundle and the posterior branch of the obturator nerve at risk."[33] Piet Hinoul, Worldwide Medical Director for the Ethicon Energy Franchise, determined that the "TVT-O trajectory is susceptible to greater variation than originally described." The authors stated, "On the basis of our findings and those of others, we feel justified to caution surgeons against an excessive feeling of safety especially when applying the TVT-O technique in certain patients." Other articles refer to the learning

[30] ETH.MESH.02229061.
[31] ETH.MESH.02340829, ETH.MESH.0230902, ETH.MESH.00860239, ETH.MESH.02340974, ETH.MESH.02340756.
[32] J. P. Spinosa, P. Y. Dubuis, and B. M. Riederer, "Transobturator Surgery for Female Stress Incontinence: A Comparative Anatomical Study of Outside-in Vs inside-out Techniques," *BJU Int* 100, no. 5 (2007).
[33] Hinoul et al., "Anatomical Variability in the Trajectory of the inside-out Transobturator Vaginal Tape Technique (Tvt-O)."; M. H. Hazewinkel, M. S. Schilthuis, and J. P. Roovers, "Stress Urinary Incontinence in Patients Treated for Cervical Cancer: Is Tvt-Secur a Valuable Treatment Option?," ibid.20, no. 3 (2009); C. M. Zahn et al., "Anatomic Comparison of Two Transobturator Tape Procedures," *Obstet Gynecol* 109, no. 3 (2007); Spinosa, Dubuis, and Riederer, "Transobturator Surgery for Female Stress Incontinence: A Comparative Anatomical Study of Outside-in Vs inside-out Techniques."; Z. Atassi et al., "Haemorrhage and Nerve Damage as Complications of Tvt-O Procedure: Case Report and Literature Review," *Arch Gynecol Obstet* 277, no. 2 (2008); H. K. Park et al., "Initial Experience with Concomitant Prolift System and Tension-Free Vaginal Tape Procedures in Patients with Stress Urinary Incontinence and Cystocele," *Int Neurourol J* 14, no. 1 (2010); J. D. Paulson and J. Baker, "De Novo Pudendal Neuropathy after Tot-O Surgery for Stress Urinary Incontinence," *JSLS* 15, no. 3 (2011).

curve associated with placement of the TVT-O.[34] Ethicon did not inform doctors of these concerns.

### 5. TVT-O PHYSICIAN TRAINING AND MARKETING

My experience, the medical literature, and Ethicon documents all attest to the need for physician training to use the TVT-O device. "Is special training needed for the safe and effective use of the device? Yes."[35] Prior to launch, Ethicon's policy was that all physicians receive training from an Ethicon preceptor:

> "Providing physician training is a very expensive proposition, however, since our business practices are guided by our CREDO, we believe in doing the right things for patents and our customers…. We still require that the physician attend a GYNECARE sponsored Professional Education event with one of our preceptors….."[36]

However, beginning in 2004, the budget for Professional Education was cut. An email August, 2004 states:

> "Because the GYNECARE business is tracking behind the Original Business Plan, the marketing spend needed to be reduced in order to deliver the committed profits…. [This] will limit the Professional Education events that can Be done…."[37]

[34] Reisenauer et al., "Transobturator Vaginal Tape inside-Out. A Minimally Invasive Treatment of Stress Urinary Incontinence: Surgical Procedure and Anatomical Conditions."
[35] ETH.MESH.00259047 at 9431.
[36] ETH.MESH.03738468.
[37] ETH.MESH.05795299.

And in 2005, "You know we are trying to get more funding, right now we do not have anything…"[38] Sales representatives were then encouraged to train themselves and physicians:

> "To me the biggest progress we can make is to reinforce the reps in 'training' themselves on TVT-O, specially the 'average' obgyns: they can sit down with them for 45 minutes, go through the procedure (cd rom and leaflets), discuss the anatomy and use a sample on a PF model…. The more we improve out ProfEd processes and ways of thinking, the more we will increase our ROI, the more money we will get: logic and discipline, right?"[39]

In my opinion and based on my personal experience as a lecturer and preceptor for TVT-O professional education, the training described in this document is grossly inadequate and puts patients at risk. In addition, the diagnosis and management of complications was not adequately discussed or taught to physicians. It also demonstrates Ethicon's interest in marketing to "average" OB-GYNS, many would have no previous experience with sling devices, performing cystoscopy, or experience operating in the transobturator space. In fact, the TVT-O IFU clearly states "Cystoscopy can be performed at the discretion of the surgeon." suggesting that it is not required and therefore the TVT-O could be performed by physicians without skills and knowledge of cystoscopy-one of the most basic procedures for evaluation and diagnosis of bladder conditions and complications. This is in contrast to the TVT Tension Free Support System for Incontinence (retropubic) where cystoscopy is described in the Instructions for Use. In review of the Gynecare TVT-O Selling Guide, they carefully crafted a sales rep strategy to

[38] ETH.MESH.05795322 at 5323.
[39] ETH.MESH.05795322 at 5324.

address clinical concerns by less experienced surgeons using templated sales rep "propaganda and statements" unsupported by data.[40]

Ethicon marketed the TVT-O as a "one-size-fits-all" device for all patients with a "reproducible" technique. Although Ethicon documents and the medical literature indicated that certain patient populations (such as obese women, "sportive" women, women of different ethnicities, diabetics, and smokers) were at higher risk for complications or had lower success outcomes. This information was not provided to doctors. Additionally, variations in patient anatomy could affect the trajectory of the trocars, directing them into more dangerous anatomical areas and resulting in higher risk for neurovascular injury.[41]

### 6. TVT-O IFU

The TVT-O Instructions for Use exclude and minimize the risks associated with the device, thus failing to give physicians the information they need to make responsible treatment choices and obtain informed consent from patients. As mentioned earlier, the only reference to pain is "transient leg pain lasting 24-48 hours" and "usually managed with mild analgesics". Adverse reactions include "transitory local irritation at the wound site and a transitory foreign

[40] ETH.MESH.02236600

[41] Ridgeway, B., et al., Variation of the obturator foramen and pubic arch of the female bony pelvis, Am J Obstet Gynecol. 2008 May, 198(5):546.el-4; Spinsosa, J., et al., Transobturator surge1y for female stress incontinence: a comparative anatomical study of outside-in vs inside-out techniques, BnJ Int. 2007 Nov, 100{5):1097-102, Epub 2007 Sep 14; Hinoul, P ., et al., Anatomical variability in the trajectory of the inside-out transobturator vaginal tape technique (TVT-0), Int Urogynecol J Pelvic Floor Dysfunction 2007, 18:1201-6; Atassi, Z., et al., Haemorrhage and nerve damage as complications of TVT-0 procedure: case report and literature review, Arch Gynecol Obstet 2008, 277:161-4, Boyles, S., et al., Complications associated with transobturator sling, Int Urogynecol J 2007, 18: 19-22; Zumbe, J. , Obturator and thigh abscess after transobturator tape implantation for stress urinary incontinence, Urol Int. 2008, 81: 483-485; ETH.MESH .02019485 (knowledge of variable obturator foramen anatomy); Zahn, C., et al., Anatomic comparison of two transobturator tape procedures, Obstet Gynecol 2007, 109:701-6; Laurikainen, E., et al., Retropubic Compared with Transobturator Tape Placement in Treatment of Urinary Incontinence, Obstectrics & Gynecology, Vol. 109, No.1, Jan. 2007 ("The number of patients complaining of postoperative groin pain was significantly greater in the TVT-0 group than in the TVT group, 21 (16%) compared with 2 (1.5%) .... " "[T]he groin pain of the TVT-0 patients persisted for 2 weeks in ten patients, for 4 weeks in three patients, and for 2 months in one patient, the rest having pain for a few days.").

body response may occur".[42] Missing from the warnings are chronic and debilitating pain, dyspareunia, nerve damage occurring months or years after insertion, sexual impairment, vaginal scarring, bladder dysfunction, mesh shrinkage/contraction, refractory overactive bladder and refractory sphincteric incontinence, and the need for multiple corrective surgeries – just to name a few.

In addition, the TVT-O IFU was never appropriately updated to reflect Ethicon's knowledge of adverse events. I reviewed documents indicating that this was a deliberate decision. Based on review of records, Dr. Meng Chen, Associate Medical Director of the Post-Market Surveillance Center of Excellence, advised updating the IFU:

> "[The patient] was given the most accurate consent for the potential adverse reaction known in 2005. However, we are in 2008 now, and there are two more TVT family products (TVTO and TVTS) on the market. Our post-market knowledge with these products are much more than what we have in the IFUs of all three types of TVTs (TVT-Abdominal, Obtuator, and Secur). My reason for bringing this point to you is may you may look into it from senior management perspective and to facilitate the IFU update for all three TVTs, particularly in the area of 'Potential Adverse Reactions'…. One of the paths for a better pre- operative is to provide an updated IFU to the operating physicians that reflecting the current knowledge of the manufacturer's on the potential adverse reactions."[43]

[42] ETH.MESH.0230902; ETH.MESH.00860239; ETH.MESH.02340974; ETH.MESH.02340756; ETH.MESH.02340829.
[43] ETH.MESH.04092868.

I also reviewed patient brochures that failed to accurately reflect the complications known to be associated with the TVT-O.[44] Although these were updated on occasions, the additional adverse events were never added to the IFU.

Reviewing the information contained in these documents is something I do on a regular basis in my practice and in my capacity as an educator of medical students, residents, and colleague physicians. In my opinion, these documents did not provide adequate information for doctors and patients to make informed choices. They did not include the severity and frequency of the complications, a complete list of potential complications, the lack of clinical data to support their use, the difficulty in removing the implant, and the chance of permanent injury/disability.

## 7. SAFER ALTERNATIVES

There are safer surgical alternatives to the TVT-O that are equally effective. This is particularly true when one considers the risk of permanent, life-changing, and disabling pain complications. Recent literature also questions the long-term durability of transobturator slings and their use in certain conditions such as Intrinsic Sphincter Deficiency.[45] It is my opinion that the Burch retropubic suspension and autologous fascial slings are safer than the TVT-O. There is just no compelling reason to market the TVT-O to physicians when there are better procedures available. This opinion is based on my experience and the peer-reviewed medical and scientific literature.[46]

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[44] E.g., ETH.MESH.05815791; ETH.MESH.08003206.

[45] A. A. Ford and J. A. Ogah, "Retropubic or Transobturator Mid-Urethral Slings for Intrinsic Sphincter Deficiency-Related Stress Urinary Incontinence in Women: A Systematic Review and Meta-Analysis," *Int Urogynecol J* (2015); Mearini L. Constantini E., Bini V., Zucchi A., Mearini E., Porena M., "Uterus Preservation in Surgical Correction of Urogenital Prolapse," *Eur Urol* 48 (2005). G. A. Tommaselli et al., "Medium-Term and Long-Term Outcomes Following Placement of Midurethral Slings for Stress Urinary Incontinence: A Systematic Review and Metaanalysis," *Int Urogynecol J* 26, no. 9 (2015).

[46] E.g., J.G. Blaivas, Chaikin, D.C., "Pubovaginal Fascial Sling for the Treatment of All Types of Stress Urinary Incontinence: Surgical Technique and Long-Term Outcome," *Urologic Clinics of North America* 38, no. 1 (2011);

Society publications such as the AUGS/SUFU "Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence" refer to midurethral slings as the "gold standard".[47] The research forming the basis for this opinion paper is primarily based on TVT studies. The TVT-O is not a "gold standard" in my opinion and different enough from the TVT procedure for reasons already cited. The American Congress of Obstetrics and Gynecology and the American Urology Association and peer-reviewed literature support the use of the alternative procedures discussed in this report.[48]

In my opinion and in my experience and based on the information above, the risks of the Gynecare TVT-O outweigh the benefits especially when alternative surgical options are available.

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M. E. Albo et al., "Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months," *J Urol* 188, no. 6 (2012); J. L. Amaro et al., "Clinical and Quality-of-Life Outcomes after Autologous Fascial Sling and Tension-Free Vaginal Tape: A Prospective Randomized Trial," *Int Braz J Urol* 35, no. 1 (2009); B. S. Wadie, A. Edwan, and A. M. Nabeeh, "Autologous Fascial Sling Vs Polypropylene Tape at Short-Term Followup: A Prospective Randomized Study," *J Urol* 174, no. 3 (2005); L. Brubaker et al., "5-Year Continence Rates, Satisfaction and Adverse Events of Burch Urethropexy and Fascial Sling Surgery for Urinary Incontinence," ibid.187, no. 4 (2012); M. M. Karram, Zoorob D., "When and How to Place and Autologous Rectus Fascia Pubovaginal Sling," *Ob Management* 24, no. 11 (2012); G. E. Leach et al., "Female Stress Urinary Incontinence Clinical Guidelines Panel Summary Report on Surgical Management of Female Stress Urinary Incontinence. The American Urological Association," *J Urol* 158, no. 3 Pt 1 (1997); J. Bidmead and L. Cardozo, "Sling Techniques in the Treatment of Genuine Stress Incontinence," *BJOG* 107, no. 2 (2000); R. R. Dmochowski et al., "Update of Aua Guideline on the Surgical Management of Female Stress Urinary Incontinence," *J Urol* 183, no. 5 (2010); D. Lee et al., "Long-Term Outcomes of Autologous Pubovaginal Fascia Slings: Is There a Difference between Primary and Secondary Slings?," *Neurourol Urodyn* (2013); G. Novara et al., "Updated Systematic Review and Meta-Analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence," *Eur Urol* 58, no. 2 (2010); J. Ogah, Cody, D.J., Rogerson, L., "Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence Inwomen: A Short Version Cochrane Review," *Neurourology and Urodynamics* 30, no. 3 (2011); F. Demirci et al., "A Retrospective Review of Perioperative Complications in 360 Patients Who Had Burch Colposuspension," *Aust N Z J Obstet Gynaecol* 39, no. 4 (1999); K. Ward et al., "Prospective Multicentre Randomised Trial of Tension-Free Vaginal Tape and Colposuspension as Primary Treatment for Stress Incontinence," *BMJ* 325, no. 7355 (2002).

[47] "Augs-Sufu Position Statement on Mesh Midurethral Slings for Sui," (2014).

[48] E.g. R. G. Rogers, "Urinary Stress Incontinence in Women," *N Engl J Med* 358, no. 10 (2008); C. G. Nilsson, "Creating a Gold Standard Surgical Procedure: The Development and Implementation of Tvt : Ulf Ulmsten Memorial Lecture 2014," *Int Urogynecol J* 26, no. 6 (2015); Dmochowski et al., "Update of Aua Guideline on the Surgical Management of Female Stress Urinary Incontinence." G. Ralph, T. Aigmueller, and P. Riss, "The Failed Idea of a "Gold Standard"," *Int Urogynecol J* 26, no. 10 (2015). American College of Obstetricians and Gynecologists, "Practice Bulletin: Urinary Incontinence in Women," no. 155 (2015).

All opinions offered in this report are made to a reasonable degree of medical certainty. I reserve the right to supplement or amend this report if new or additional information is reviewed or becomes available.

## III. DATA CONSIDERED IN FORMING MY OPINIONS

I considered the documents identified in the footnotes/references section of this report.

## IV. EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF MY OPINIONS

I may use documents that I reviewed and which are identified above, female pelvic floor models and illustrations, samples of the TVT-O kit, and summaries of literature that I may prepare.

## V. COMPENSATION FOR MY REVIEW, STUDY AND TESTIMONY

For case review, consultation, and conference calls: $1,000/hr in 15 mins increments

There is a 50% premium charged on these rates for deliverables within 30 days

For deposition and trial testimony, $6,000/half day and $10,000/day in 4 hour increments

For court appearance, $12,000/day

For travel time outside 4 (half day) and 8 hours (full day), $250/hour in 30 mins increments

Full payment for cancellation/rescheduling within 2 weeks

50% payment for cancellation/rescheduling within 4 weeks

## VI. OTHER CASES IN WHICH I HAVE TESTIFIED AS AN EXPERT AT TRIAL OR BY DEPOSITION IN THE LAST FOUR YEARS

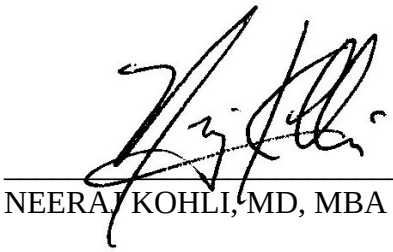
2012 - Scott vs Bard – Defense – Trial Testimony

2012 -2013 - Russell vs Miklos – Defense – Deposition, Trial Testimony

2013 – Derouen vs Park Place Surgery – Plaintiff – Deposition

2013 - Cappacione vs Syed – Defense – Trial Testimony

2013 – Beier vs Dersham – Plaintiff – Deposition



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